

REMARKS/ARGUMENTS

Claim Objection

Claims 2-11 were objected to for failing to recite the preamble term "kit". The applicant agrees and amended the claims accordingly.

35 USC § 112, 1st paragraph

Claims 1-11 were rejected under 35 USC § 112, 1st paragraph as lacking corresponding written description with respect to the term "kit". While the applicant agrees that the term "kit" was not used in the specification, it is pointed out that the specification need not provide written description *ipsis verbis* as noted in MPEP 2163IIA3(a).

If a skilled artisan would have understood the inventor to be in possession of the claimed invention at the time of filing, even if every nuance of the claims is not explicitly described in the specification, then the adequate description requirement is met. See, e.g., *Vas-Cath*, 935 F.2d at 1563, 19 USPQ2d at 1116; *Martin v. Johnson*, 454 F.2d 746, 751, 172 USPQ 391, 395 (CCPA 1972) (stating "the description need not be in *ipsis verbis* [*i.e.*, "in the same words"] to be sufficient"). In the instant case, the specification adequate description on page 12:

"...a dietary supplement selected from the group of a nutritionally acceptable form of boron, calcium, magnesium, and vitamin D is provided...[and]...printed information is provided that a combination of the nutritionally acceptable form of boron with at least one of the nutritionally acceptable form of calcium, magnesium, and vitamin D promotes bone health.."

and

"...printed information may advantageously include a...package insert, and/or label on the dietary supplement, which may further include information that the nutritionally acceptable form of boron increases a steroid concentration (*e.g.*, estrogen, testosterone, or 25-hydroxy vitamin D3) in the human. ..."

Thus, it should be apparent that the applicant was in the possession of the claimed invention at the time the application was filed.

35 USC § 103(a)

Claims 1-17 were rejected under 35 USC § 103(a) as being obvious over Miljkovic (U.S. Pat. No. 5,962,049) in view of Naghii, Nielsen, Volpe, and FDA Talk Paper. The applicant respectfully disagrees, especially in view of the amendments made herein.

With respect to the examiner's characterization of Miljkovic on page 3 of the office action, the applicant agrees. The applicant also agrees to some extent with the characterization of Naghii, Nielsen, Volpe, and the Talk Paper. However, the examiner did not specify the types of boron compounds in these references, which is significant to the following discussion. The office then set out to argue on page 4, last paragraph, that the prior art disclosed carbohydrate boron complexes, and that boron would be important for bone health. It should be noted that the generic statement of "boron would be important for bone health" is not contested.

However, it is stressed that not all 'boron' is the same. It is also stressed that the claimed subject matter is limited to an isolated carbohydrate-boron complex having a boron portion and at least one carbohydrate ligand complexed to the boron portion with a boron-ligand association constant of at least 2,500. Throughout the entire office action, it appears as though the office used all boron compounds indiscriminately, irrespective their chemical composition.

The applicant once again points to the fact that the carbohydrate-boron complex must have a boron-ligand association constant of at least 2,500. The significance of such association cannot be ignored. K_A is $-\log ([\text{boron}][\text{ligand}]/[\text{complex}])$. ***Thus, complexes having a $K_A \geq 2500$ will be complexes in which boron is very tightly bound.*** Such is in contrast to ordinarily used boron salts, which readily dissociate into their constituent ionic parts.

Consequently, the examiner's reasoning on page 5 of the office action that "... one of ordinary skill in the art would have been motivated to modify the prior art as above with the expectation that the carbohydrate-boron complex would be effective in increasing steroid concentration in humans..." is not persuasive. On the contrary, ***the person of ordinary skill in the art would be disincentivized to use complexes in which boron is very tightly bound as one would not expect boron to be bioavailable.*** As can be seen from the attached experimental data, the complex is so stable that it survives intestinal passage and is present in measurable quantities

in the blood stream. Remarkably, ***despite such strong association, bioavailability is even higher than reference compounds with significantly lower K_A values*** as can be taken from the attached data. Such finding is contrary to accepted wisdom and serves *per se* as a strong indicator of non-obviousness (*In re Hedges*, 783 F.2d 1038, 228 USPQ 685 (Fed. Cir. 1986)).

Moreover, the office also failed to set forth a reason as to why the person of ordinary skill in the art would have had any motivation for combination of the references as cited. Indeed, the office merely stated that:

"... one of ordinary skill in the art ***would have been motivated to modify the prior art*** as above with the expectation that the carbohydrate-boron complex would be effective in increasing steroid concentration in humans, that increasing serum estradiol would increase bone density, that boron's effect on bone metabolism would be facilitated by the addition of calcium, magnesium and vitamin D and that the dietary supplement can be in any form desired, including pills and mixtures with suitable excipients, binders and carriers and other compounds included as known in the pharmaceutical arts...(emphasis added)"

Just a statement that the PHOSITA would be motivated is insufficient in the absence of reasons for such motivation. This requirement was reiterated in the Foccarino memo stating that "...in formulating a rejection under 35 U.S.C. 5 103(a) based upon a combination of prior art elements, it remains necessary to identify the reason why a person of ordinary skill in the art would have combined the prior art elements in the manner claimed..."

As pointed out above, the examiner's argument of expectation of success in increasing steroid concentration in humans is ill founded in view of the high K_A of the claimed complexes. Chelation therapy is a well-known aspect of high- K_A complexes that reduce bioavailability of the bound metal (see e.g., Environ Health Perspect. 2002 Oct;110 Suppl 5:887-90, or Environ Health Perspect. 1998 Dec;106 Suppl 6:1585-7.). Clearly, the PHOSITA would not have a reasonable expectation of success. ***Should the office insist in such reasoning, the applicant respectfully request that the office provide objective evidence that substantiates the proposed expectation.***

The examiner further stated in the office action on page 7 that "...the Applicant provides no evidence that carbohydrate-boron compositions of the '049 patent would not promote bone

health..." It is not clear what the office intends to express. In case the office intended to argue that the compositions of the '049 patent would inherently promote bone health, the applicant respectfully requests that the office provide a basis in fact and/or technical reasoning to reasonably support the determination that the ***allegedly inherent characteristics necessarily flow from the teachings*** of the applied prior art. See *In re Robertson*, 169 F.3d 743, 745, 49USPQ2d 1949, 1950-51 (Fed. Cir. 1999). The examiner has not provided persuasive support for an inherency theory. Inherency ***cannot be established based on conjecture and/or probabilities or possibilities***. See *In re Oelrich*, 666 F.2d 578, 581, 212 USPQ, Appeal No. 2004-0896 Application No. 09/751,774 Page 6323, 326 (CCPA 1981); *Ex parte Skinner*, 2 USPQ2d 1788, 1788-1789(Bd. Pat. App. & Int. 1986).

Furthermore, and with respect to the examiner's statement on page 8 that the applicant had not set forth specific dosage amounts or ranges, the applicant notes that claim 12 and all claims dependent thereon require administration of the carbohydrate-boron complex under a protocol effective to increase the steroid concentration in the human.

Based on the amendments and arguments provided above, the examiner's concerns and rejections should be overcome. In view of the present amendments and arguments, the applicant believes that all claims are now in condition for allowance. Therefore, the applicant respectfully requests that a timely Notice of Allowance be issued in this case.

Respectfully submitted,
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